

**UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK**

LOUISIANA WHOLESALE DRUG CO., INC.,

Plaintiff,

v.

SANOFI-AVENTIS, SANOFI-AVENTIS
U.S., LLC and AVENTIS
PHARMACEUTICALS, INC.,

Defendants.

)
) Civil Action No. 07-cv-7343 (HB)
)

) Hon. Harold Baer, U.S.D.J.
) ECF CASE
)

**MEMORANDUM OF POINTS AND AUTHORITIES
IN SUPPORT OF DEFENDANTS SANOFI-AVENTIS US LLC AND
AVENTIS PHARMACEUTICALS INC.'S MOTION TO DISMISS
THE COMPLAINT FOR FAILURE TO STATE A CLAIM**

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INTRODUCTION

This case presents the question whether a branded drug manufacturer may be stripped of its *Noerr-Pennington* antitrust immunity for bringing safety and efficacy concerns about generic versions of a drug to the attention of the Food and Drug Administration (the “FDA”). Plaintiff Louisiana Wholesale Drug Co., Inc. (“Louisiana Wholesale”) appears to believe that conclusory assertions about the objective merit of a petition and speculative allegations about when and why a party filed it should strip the petitioning party of its First Amendment immunity and leave it vulnerable to antitrust claims that its conduct delayed FDA approval of generic drugs. Louisiana Wholesale is patently wrong. Neither its view of the law nor its characterization of the documents underlying the complaint (the “Complaint”) supports the cause of action Louisiana Wholesale seeks to advance against Aventis Pharmaceuticals Inc. and sanofi-aventis us llc (collectively, “Aventis”), companies that market and sell Arava® (chemical name leflunomide) in the United States.¹ Specifically, the Complaint should be dismissed for three principal reasons:

First, the petitioning conduct at issue falls well within the antitrust immunity prescribed by the *Noerr-Pennington* doctrine. Assuming that a “sham” exception to *Noerr-Pennington* could apply here at all, Louisiana Wholesale has failed to assert anything more than conclusory allegations that Aventis’ conduct was “objectively baseless,” and has failed to cross the first and necessary hurdle to stripping Aventis of its First Amendment immunity.

Second, Louisiana Wholesale lacks antitrust standing to assert these claims. It has failed to state any facts supporting its allegation that Aventis’ conduct delayed FDA approval of

¹ Although the Complaint names sanofi-aventis as a defendant, that entity is not joining the present motion since the parties continue to discuss whether sanofi-aventis belongs in the case at all. Absent a negotiated resolution to that question sanofi-aventis will file its own motion to dismiss the Complaint on October 19, 2007, a date the parties have proposed to the Court in their agreed-upon case management order (submitted to the Court on October 11, 2007).

generic leflunomide, or to demonstrate that Louisiana Wholesale would be an efficient enforcer of the antitrust laws.

Finally, Louisiana Wholesale has not satisfied its burden of alleging facts (rather than unsupported assertions) that there are no reasonable substitutes for leflunomide, and consequently has failed to adequately allege a “relevant market” for a claim arising under Section 2 of the Sherman Act.

FACTUAL BACKGROUND

A. The Right to Petition the FDA

Any person or entity may file a petition asking the FDA to take (or to refrain from taking) a particular action, *see* 21 C.F.R. § 10.30, and the docket for any such petitions is open for the world to see: <http://www.fda.gov/ohrms/dockets/default.htm> (last visited Oct. 13, 2007).

Although applicable regulations permit the Commissioner 180 days to review a citizen petition in the ordinary course, 21 C.F.R. § 10.30(e)(2), the regulations also provide that the filing of a citizen petition *shall not* “stay or otherwise delay *any* administrative action by the Commissioner,” 21 C.F.R. § 10.35(d) (emphasis added).

B. Innovator and Generic Drug Approval Processes

Under the Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 *et seq.* (the “FDCA”), new drug manufacturers must file a comprehensive New Drug Application (“NDA”) and submit specific data demonstrating the safety and efficacy of a proposed new drug. In exchange for the substantial amount of work required to prepare an NDA — including, among other things, clinical trials — the FDCA rewards pioneer drug manufacturers with differing periods of marketing exclusivity. 21 U.S.C. §§ 355, 355a.

The Hatch-Waxman Act (the “Act”), 21 U.S.C. §355 (2003), created a process for reviewing and approving generic drugs upon expiration of the NDA holder’s exclusivity rights.

Specifically, the Act created a pathway by which generic drug manufacturers could file an Abbreviated New Drug Application (“ANDA”), rely on the safety and effectiveness data submitted in the original NDA, show that its drug was bioequivalent to the innovator drug, and (with limited exceptions) copy the branded drug manufacturer’s labeling information. 21 U.S.C. § 355(j)(2)(A).²

The Act did not, however, make the FDA’s ANDA review and approval process transparent. The very existence and substance of an ANDA is confidential, *see* 21 C.F.R. § 314.430(b) and (d), and unless an NDA holder possesses certain patent rights entitling it to notice of the ANDA under the Act, the pioneer drug manufacturer may not know that an ANDA has been filed unless and until it has been approved.

C. The Leflunomide NDA

Leflunomide is a pharmaceutical compound used to treat active rheumatoid arthritis; to reduce signs, symptoms, and structural damage associated with the disease; and to improve patients’ physical function. Compl. ¶ 1.³ Aventis, the innovator manufacturer of the drug, prepared an NDA to market and sell 10mg, 20mg, and 100mg leflunomide tablets to be sold under the trade name Arava® (“Arava”). Compl. ¶ 44. Because the NDA relied upon clinical trials incorporating a loading dose regimen of 100mg tablets taken on each of three days, *see* Exh. 1, Tab 3 at 5, the FDA required Aventis to include information about the 100mg loading dose

² According to statistics available when Aventis filed the citizen petition at issue in this case, the FDA took an average of twenty months to review an ANDA. *See* <http://www.fda.gov/oc/initiatives/generics/whitepaper.html> (last visited on October 15, 2007).

³ According to the citizen petition Aventis filed with the FDA, leflunomide is one of a number of disease modifying anti-rheumatoid drugs (“DMARDs”). *See* Exh. 1, Tab 6. Although Louisiana Wholesale attached the citizen petition and the FDA’s response to the Complaint, this Court may take judicial notice of the entire citizen petition docket (officially part of the FDA’s administrative record, *see* 21 C.F.R. § 10.30(i), and attached hereto as Exhibits 1-6) and certain correspondence between Generic Manufacturers and the FDA (attached hereto as Exhibit 7), upon which plaintiffs have clearly relied in drafting their complaint. *See ATSI Commc’ns, Inc. v. Shaar Fund, Ltd.*, 493 F.3d 87, 98 (2d Cir. 2007).

regimen in the drug's approved label. Compl. ¶ 45. The FDA explicitly refused to allow Aventis to substitute five 20mg tablets as an alternative to the 100mg tablet without additional clinical trials establishing that five 20mg tablets of Arava are bioequivalent to one 100mg tablet of Arava. Exh. 1 at 2. The FDA approved the NDA on September 10, 1998. Compl. ¶ 50. Although Aventis enjoyed exclusive rights to market all three dosages for five years from the date of FDA approval plus an additional six months for pediatric exclusivity, Compl. ¶ 46, Aventis stopped selling 100mg Arava tablets in September 2002. Compl. ¶ 48. Instead, Aventis provided the three-tablet loading dose free of charge to physicians. Compl. ¶ 48.

D. The Leflunomide ANDAs and Aventis' Citizen Petition

Aventis' marketing exclusivity expired on March 10, 2004, paving the way for generic drug companies to file ANDAs for non-branded versions of the drug. Compl. ¶ 50. According to the Complaint, Kali Laboratories, Barr Laboratories, Teva Pharmaceuticals, Apotex Corp. and Sandoz, Inc. (collectively, the "Generic Manufacturers") filed ANDAs for generic leflunomide on or about March 10, 2004, and sought approval to market 10mg and 20mg tablets. Compl. ¶ 51. Because Arava was not covered by a patent when the Generic Manufacturers were permitted to file ANDAs for generic leflunomide, Compl. ¶ 46, Aventis was not entitled to notice that they had done so.

On March 31, 2005, Aventis submitted a citizen petition to the FDA. Compl. ¶ 52. Acting "on information and belief" (since it had no way of knowing) that generic drug companies had filed ANDAs for 10mg and 20mg – but not 100mg – leflunomide tablets, Aventis expressed its concern that the Generic Manufacturers were "seeking to include a loading dose of five 20mg tablets" (something Aventis had not been permitted to do without additional bioequivalence testing) or "seeking to exclude the loading dose altogether" (something the Act would not permit a Generic Manufacturer to do because the generic drug would not be as safe or

effective as Arava). Exh. 1 at 3. On the latter point, Aventis explained that the loading dose would permit patients to achieve a steady-state concentration of leflunomide in three days. *Id.* Without a loading dose, patients would have to wait for nearly two months before reaching the same therapeutic result; in the interim, the patient would continue to incur more joint damage and deterioration. *Id.* at 3-5.⁴ Accordingly, Aventis asked the FDA not to permit the Generic Manufacturers to “omit the loading dose information” or to “simply substitute ‘five 20mg tablets’ for the reference to ‘one 100mg tablet’ in the loading dose section” without additional bioequivalence testing. *Id.* at 5-6.

Two of the Generic Manufacturers filed responses to the citizen petition. Kali Laboratories objected to the timing of the petition; argued that it was not obligated to market all three dosage strengths; and suggested that its labeling need not include the loading dose information or that its labeling should be permitted to refer doctors to Arava’s loading dose information. Exh. 3 at 1-3. Olson, Frank & Weeda, a law firm acting on behalf of another Generic Manufacturer, acknowledged that the petition “seems to be credible,” but went on to attack it on the erroneous belief that Aventis no longer manufactured 100mg tablets. Exh. 4 at 2-3.

Although the FDA officially denied the citizen petition on September 13, 2005, Compl. ¶ 62, it did so only after a seven-page discussion of its reasons for denying the petition, culminating with the statement that “[i]n light of the discussion above, FDA will require the labeling for generic leflunomide products to include the labeling approved for [Arava] concerning the use of a 100mg loading dose.” Exh. 6 at 7 (emphasis added). On the same day,

⁴ In support of this argument the citizen petition cited and attached numerous articles, which identified sulphasalazine and methotrexate (among others) as additional and comparable rheumatoid arthritis drugs. Exh. 1, Tab 6 at 11-12.

the FDA approved the Generic Manufacturers' ANDAs. Compl. ¶ 62. Generic leflunomide tablets entered the market the following day. Compl. ¶ 62. Notably, the FDA's letters to the Generic Manufacturers reflected the number and dates of amendments to the ANDAs, including seventeen amendments filed after Aventis filed the citizen petition, and one amendment filed just five days before the FDA denied the citizen petition. *See generally* Exh. 7.

E. Louisiana Wholesale's Sham Allegations

The Complaint alleges that the citizen petition was a "sham" intended only to delay FDA approval of generic leflunomide. Compl. ¶ 7. Louisiana Wholesale claims that Aventis' alleged misconduct illegally extended Aventis' market exclusivity for Arava and unreasonably restrained generic competition for leflunomide. Compl. ¶¶ 9-10. Louisiana Wholesale contends that it and other entities that purchased Arava directly from Aventis at any time from March 2005 to the date upon which the alleged anticompetitive effects of Aventis' conduct ceased paid supra-competitive prices for the drug, Compl. ¶ 16, and are entitled to treble damages for the difference between a pre-generic and post-generic price for leflunomide. Compl. ¶ 18.

LEGAL STANDARD

Federal Rule of Civil Procedure 12(b)(6) requires dismissal of claims where the supporting allegations fail "to raise a right to relief above the speculative level." *Bell Atl. Corp. v. Twombly*, 550 U.S. ___, 127 S.Ct. 1955, 1965 (2007) (citing 5 C. Wright & A. Miller, Federal Practice and Procedure § 1216, pp. 235-236 (3d ed. 2004)). Specifically, "something beyond the mere possibility of loss causation must be alleged, lest a plaintiff with 'a largely groundless claim' be allowed to 'take up the time of a number of other people, with the right to do so representing an *in terrorem* increment of the settlement value.'" *Id.* at 1966 (quoting *Dura Pharm., Inc. v. Broudo*, 544 U.S. 336, 347 (2005)). These principles apply with particular

urgency to antitrust litigation, in light of the unusual burden and expense of discovery in those cases. *See id.* at 1967.

When evaluating a motion to dismiss for failure to state a claim, the Court “must consider the complaint in its entirety, as well as other sources courts ordinarily examine when ruling on Rule 12(b)(6) motions to dismiss, in particular, documents incorporated into the complaint by reference, and matters of which a court may take judicial notice.” *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, ___ U.S. ___, 127 S.Ct. 2499, 2509 (2007); *see also ATSI Commc’ns, Inc. v. Shaar Fund, Ltd.*, 493 F.3d 87, 98 (2d Cir. 2007) (holding that court ruling on motion to dismiss may consider “any written instrument attached to the complaint, statements or documents incorporated into the complaint by reference . . . and documents possessed by or known to the plaintiff and upon which it relied in bringing the suit”). The Court “need not feel constrained to accept as truth conflicting pleadings that make no sense, or that would render a claim incoherent, or that are contradicted either by statements in the complaint itself or by documents upon which its pleadings rely, or by facts of which the court may take judicial notice.” *In re Livent, Inc. Noteholders Sec. Litig.*, 151 F. Supp. 2d 371, 405-06 (S.D.N.Y. 2001) (citing *Hirsch v. Arthur Andersen & Co.*, 72 F.3d 1085, 1095 (2d Cir. 1995)).

ARGUMENT

I. AVENTIS’ CITIZEN PETITION IS IMMUNE FROM ANTITRUST LIABILITY UNDER THE NOERR-PENNINGTON DOCTRINE

Aventis’ citizen petition reflected classic First Amendment petitioning activity. It is therefore immune from antitrust liability under the *Noerr-Pennington* doctrine, which the Supreme Court developed in a trilogy of cases addressing the antitrust immunity provided to a party petitioning the government for protection or redress. *See E. R.R. Presidents Conf. v. Noerr Motor Freight, Inc.*, 365 U.S. 127, 138 (1961); *United Mine Workers of Am. v. Pennington*, 381

U.S. 657, 669-71 (1965); *Cal. Motor Transp. Co. v. Trucking Unlimited*, 404 U.S. 508, 510-11 (1972). Moreover, because the Complaint fails to allege facts sufficient to show that the citizen petition was objectively baseless, Louisiana Wholesale has not demonstrated that any exception to *Noerr-Pennington* immunity applies to strip Aventis of its antitrust immunity.

A. The Filing of a Citizen Petition Is Classic First Amendment Activity

As the Supreme Court recognized in *Noerr*, parties who petition the government in order to influence government decisions may well have financial interests in the outcome of the deliberations. *See Noerr*, 365 U.S. at 139. But exposing those parties to antitrust liability would “deprive the government of a valuable source of information and, at the same time, deprive the people of their right to petition in the very instances in which that right may be of the most importance to them.” *Id.* Accordingly, the Court in *Noerr* deemed it “clear” that antitrust liability could not attach to “mere solicitation of governmental action with respect to the passage and enforcement of laws.” *Id.* at 138. And in *California Motor Transport*, the Court determined that the same immunity should apply to petitioning before administrative agencies and courts, holding that antitrust liability based on such petitioning would be no less “destructive of rights of association and of petition.” 405 U.S. at 510-11; *see also Prof'l Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc.*, 508 U.S. 49, 56-57 (1993).

In the administrative context, lower courts have routinely applied *Noerr-Pennington* immunity to protect parties from antitrust liability arising from their objections to permit applications sought by business rivals. For example, in *Potters Medical Center v. City Hospital Association*, 800 F.2d 568 (6th Cir. 1986), the Sixth Circuit upheld the immunity of a hospital that objected to the proposed construction of a rival facility. *Id.* at 579. The applicable regulatory regime, the court observed, “anticipate[d] such participation by private health care providers.” *Id.* at 578. By objecting to the construction, the hospital “was essentially asking that

[the new facility] be required to comply with the same regulations with which [the existing hospital] was required by law to comply.” *Id.* at 579. The court thus deemed the objecting party’s petitioning activity “precisely the type of conduct intended to be insulated by *Noerr-Pennington*.” *Id.* at 578; *see also, e.g., Kottle v. Northwest Kidney Ctrs.*, 146 F.3d 1056, 1059 (9th Cir. 1998) (finding “no difficulty” applying *Noerr-Pennington* immunity to a “lobbying effort” by healthcare providers seeking to “influence a state administrative agency’s decision” regarding approval of a new facility); *Bath Petroleum Storage, Inc. v. Market Hub Partners, L.P.*, 129 F. Supp. 2d 578, 594-97 (W.D.N.Y. 2000) (applying *Noerr-Pennington* to preclude liability based on a business competitor’s environmental and safety-related objections to approval of a proposed natural gas storage facility).

Aventis’ request of the FDA is protected by the same *Noerr-Pennington* immunity. The citizen petition, as the name indicates, constituted classic petitioning activity and requested specific action from a government regulator. *See* Exh. 1 at 1. By seeking specific relief from the FDA, Aventis exercised its First Amendment right “to petition the Government for a redress of grievances,” U.S. Const. amend. I, thus triggering the *Noerr-Pennington* immunity for “attempts to influence the passage or enforcement of laws,” *Noerr*, 365 U.S. at 135.

Aventis’ action was indistinguishable from the administrative petitioning conduct courts found immune in the cases noted above. As an initial matter, the “citizen petition” — a type of agency filing specifically contemplated by FDA regulations, *see* 21 C.F.R. § 10.30 — reflected a form of petitioning specifically “anticipate[d]” by the applicable regulatory regime. *Potters Med. Ctr.*, 800 F.2d at 578. Moreover, Aventis (like the hospital in *Potters Medical Center*) “essentially ask[ed]” that generic applicants “be required to comply with the same regulations with which [Aventis] was required by law to comply.” *Id.* at 579.

The citizen petition reflected legitimate concerns that any ANDAs (which Aventis could not review before filing the petition, since ANDAs are confidential) seeking approval for generic 10mg and 20mg leflunomide tablets (but not a 100mg “loading dose”) would not be as effective as Arava in modifying the effects of rheumatoid arthritis, and that the same safety and efficacy concerns the FDA raised with Aventis about the bioequivalence of five 20mg tablets to a 100mg tablet should also apply to any Generic Manufacturers. Such a request for evenhanded administration of regulatory requirements reflected “precisely the type of conduct intended to be insulated by *Noerr-Pennington*.” *Potters Med. Ctr.*, 800 F.2d at 578.

B. The Sham Exception to the *Noerr-Pennington* Doctrine Cannot Apply to the Citizen Petition As a Matter of Law

Despite the manifest immunity of Aventis’ petitioning conduct, Louisiana Wholesale is attempting to base a claim on the “sham” exception to the *Noerr-Pennington* doctrine. Compl. ¶ 58 (alleging in conclusory fashion that the citizen petition was “objectively baseless”). But petitioning conduct constitutes a “sham” only if (1) the petition or lawsuit is “objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits” and (2) the petitioning party acted with the subjective intent of interfering “*directly* with the business relationships of a competitor through the use of the governmental *process* . . . as an anticompetitive weapon.” *Prof'l Real Estate Investors*, 508 U.S. at 60-61 (internal quotation marks and citations omitted). Under this two-part test, the Supreme Court directed lower courts to consider the first requirement before reaching the second. *Id.* at 60.

If the antitrust defendant had probable cause to institute the challenged legal proceedings — in other words, if the defendant had “*no more than a reasonable belief that there is a chance that a claim may be held valid upon adjudication*” — the challenged conduct was objectively reasonable as a matter of law. *Id.* at 63 (emphasis added and internal quotation

marks and alterations omitted) (citing, *inter alia*, Restatement (Second) of Torts § 675, cmt *e* (1977)). One well-established corollary of this principle is that the sham exception is categorically unavailable with regard to positions advocated by the petitioner and embraced by the agency. Thus, where the substance of a petition is actually adopted by the government, it “certainly cannot be characterized as a sham.” *Id.* at 58 (internal quotation marks omitted); *see also, e.g., Bayou Fleet, Inc. v. Alexander*, 234 F.3d 852, 862 (5th Cir. 2000) (observing that “[b]ecause [petitioning parties] achieved favorable results, their endeavors were, by definition, reasonable” and thus qualified for *Noerr-Pennington* immunity).

Similarly, where a petition simply urges the government to adhere to positions adopted by the agency in earlier rulings, the sham exception cannot apply. *See, e.g., Potters Med. Ctr.*, 800 F.2d at 579 (applying immunity to petition requesting that a permit applicant “be required to comply with the same regulations” that governed earlier applicants). Petitioning conduct cannot be deemed a sham where it actually persuades the decisionmaker or it is based on the decisionmaker’s own prior determinations, since a decisionmaker can be “realistically expect[ed]” to adhere to its own decisions. *Prof’l Real Estate Investors*, 508 U.S. at 60.

Courts apply this limitation upon the sham exception forcefully. When a petitioner’s position is adopted only in part or at a preliminary stage, the government’s adoption of the challenged position may foreclose the application of the sham exception as a matter of law. *See, e.g., Potters Med. Ctr.*, 800 F.2d at 578-79 (holding that the petitioning party’s “relative success” justified *Noerr-Pennington* immunity where objections led to a preliminary injunction that was partially stayed on appeal); *In re Circuit Breaker Litig.*, 984 F. Supp. 1267, 1274 (C.D. Cal. 1997) (holding that a preliminary injunction in one suit and favorable jury findings in another supported *Noerr-Pennington* immunity even though the opposing party prevailed on certain

affirmative defenses in the second case). This legal limitation upon the scope of the sham exception renders it inapplicable here. Aventis' petition did not seek to impose novel conditions on generic leflunomide tablets. To the contrary, as noted above, Aventis requested that the FDA impose the very conditions on the Generic Manufacturers that the agency had imposed on Aventis. *See Potters Med. Ctr.*, 800 F.2d at 579.

Moreover, the conclusion that the sham exception does not apply here is bolstered because the subject of Aventis' petitioning activity — confidential agency proceedings regarding approval of FDA-regulated drugs — makes immunity essential to protecting the public interests served by the *Noerr-Pennington* doctrine. As the Supreme Court explained in *Noerr*, immunity for petitioning conduct is designed to protect the petitioning party's First Amendment right to seek redress of grievances. But it also safeguards a "valuable source of information" *for the government*, namely, access to the views and concerns of interested parties whose perspectives are necessary for making informed policy decisions. *Noerr*, 365 U.S. at 139; *see also, e.g., BE & K Constr. Co. v. NLRB*, 536 U.S. 516, 532 (2002) (observing that protection of petitioning activity "allow[s] the public airing of disputed facts," "raise[s] matters of public concern," and "promote[s] the evolution of the law" (internal quotations omitted)). Applying the sham exception to positions actually adopted by the agency itself would discourage parties from calling attention to applicable precedents, and deprive the government of necessary public input in contravention of the policies underlying the *Noerr-Pennington* doctrine.

The threat of treble damages should not be permitted to overwhelm the need for disclosure to an agency, particularly where the agency's decisions could have serious public health consequences. It is not surprising, then, that numerous courts have applied *Noerr-Pennington* immunity to the expression of comparable health and safety concerns. *See, e.g., In*

re Circuit Breaker Litig., 984 F. Supp. at 1275 (rejecting antitrust claims based on safety and trademark-related complaints filed with an administrative agency regarding certain rebuilt circuit breakers); *Bath Petroleum Storage*, 129 F. Supp. 2d at 594-97 (dismissing antitrust claims based on safety and environmental objections asserted in agency proceedings regarding approval of an underground natural gas storage facility); *Sessions Tank Liners, Inc. v. Joor Mfg., Inc.*, 827 F.2d 458, 462 (9th Cir. 1987) (recognizing immunity for complaints filed with a private standard-setting body in part because a contrary result would have exposed complaining parties to liability simply for calling attention to “true and persuasive information about the safety hazards of a competitor’s product”), *vacated and remanded on other grounds*, 487 U.S. 1213 (1988), *immunity recognized following remand*, 17 F.3d 295 (9th Cir. 1994).

Noerr-Pennington immunity is as essential in this case as it was in the cases cited above. Because ANDAs are confidential, interested parties cannot be certain that ANDA applicants are proposing to adhere to the same safety and efficacy standards imposed on the innovator drug manufacturer, and cannot know whether their objections to a particular aspect of an ANDA will be germane to the FDA’s evaluation of the ANDA. Robust *Noerr-Pennington* immunity is essential to ensuring that such parties do not withhold critical health and safety concerns from the FDA.

C. Louisiana Wholesale Has Not Alleged Sufficient Facts to Invoke an Exception to *Noerr-Pennington* Immunity

Even if the “sham” exception applied to the citizen petition, the allegations in the Complaint effectively put the cart before the horse. The Complaint relies heavily on atmospherics and unfounded speculation regarding the *subjective* motive behind the filing of the citizen petition, *see* Compl. ¶¶ 49-54, but it fails to allege *any* facts sufficient to demonstrate that the citizen petition was *objectively* baseless, the first hurdle of the *Prof’l Real Estate Investors*

test. The Complaint attaches copies of and quotes selectively from the citizen petition and the FDA's response to it, but Louisiana Wholesale has omitted any reference to the remainder of the citizen petition docket, including: (1) comments submitted by two of the generic companies whose ANDAs were implicated by the citizen petition, (2) Aventis' response to those comments, and (3) the FDA's letters approving the generic leflunomide ANDAs.⁵

These publicly-available documents (which Louisiana Wholesale certainly reviewed when preparing the Complaint, as it was required to do by Federal Rule of Civil Procedure 11 and as evidenced by the fact that it referenced information from the Generic Manufacturers' approval letters in the Complaint) demonstrate that the citizen petition was not "objectively baseless." First, although the Complaint summarily asserts that Aventis' concerns were meritless because none of the Generic Manufacturers ultimately sought approval to use five 20mg leflunomide tablets as a 100mg loading dose, the Generic Manufacturers' comments suggest that at least one generic company initially sought to substitute five 20mg tablets in place of the 100mg loading dose. Second, the FDA's response and remedy demonstrates that Aventis' petition rested on a reasonable foundation.

The Complaint summarily asserts that Aventis had "no basis" for its belief that pending ANDAs sought either to include a loading dose of five 20mg tablets, or to exclude the loading dose altogether. Compl. ¶ 57.⁶ But Kali Laboratories' response to the petition suggests that it may have asked the FDA to eliminate the 100mg loading dose or to substitute five 20mg tablets

⁵ As indicated in note 3, *supra*, the Court may consider these materials in ruling on this Rule 12(b)(6) motion, and is not bound by unsupported allegations to the contrary. *ATSI*, 493 F.3d at 98; *Livent*, 151 F. Supp. 2d at 405-06.

⁶ The Complaint also contains the remarkable assertion that Aventis' belief about the ANDAs constituted a "false statement." Compl. ¶ 57. As noted above, Aventis did not have access to the ANDAs and had no way of knowing what they said. Louisiana Wholesale stopped short of alleging that Aventis was omniscient, which would be the only basis on which to conclude Aventis knew a particular statement to be false.

in its place. *See* Letter from Kali Laboratories to FDA, May 12, 2005, at 2 (attached hereto as Exhibit 3). In its response to the citizen petition, Kali took the position that the loading dose was unnecessary for effective treatment. *See id.* Kali acknowledged that some patients might benefit from the loading dose, but suggested that physicians could simply refer to *Arava*'s label for information about the loading dose. *Id.* (“[P]rescribing physicians can consult *the labeling of the Arava package insert* for loading dose information using [the 100mg tablet].”) (emphasis added). More to the point, the second response to the petition — filed on behalf of a generic applicant — explicitly admitted that “the petition seems to be credible.” Letter from Arthur Y. Tsien to FDA, May 18, 2005, (the “Olsson Letter”) at 2 (attached hereto as Exhibit 4).⁷

These responses clearly demonstrate that Aventis was “reasonable” in believing there was “a chance that [its] claim [would] be held valid upon adjudication.” *Prof'l Real Estate Investors*, 508 U.S. at 62-63. Viewed in light of the documents upon which the Complaint relies, Louisiana Wholesale's allegations do not demonstrate — let alone suggest — that the citizen petition was “objectively baseless.”

The FDA's response to the citizen petition likewise establishes that the petition had objective merit. Far from rejecting Aventis' labeling concerns as substantively baseless, the FDA spent seven pages responding to the petition and expressly acknowledged the correctness of the substantive points raised in it (although it chose to address them by means of an alternative remedy). The FDA did not condition approval of 10mg and 20mg generic tablets on the provision of 100mg tablets or bioequivalence studies, as Aventis had suggested, but the FDA determined “*in light of the discussion*” generated by the petitioning process that it would require

⁷ The Olsson Letter went on to argue that the FDA should not grant the petition, but its argument was of little relevance to the FDA's deliberations (and should carry absolutely no weight here) because it proceeded from the erroneous belief that Aventis no longer *manufactured* a 100mg *Arava* tablet. *Id.* (alleging that “Aventis had discontinued 100mg *Arava* tablets.”).

the Generic Manufacturers to include “the labeling approved for [Arava] concerning the use of a 100-mg loading dose.” *See* Exh. 6 at 7.

For all the foregoing reasons, the citizen petition constituted protected First Amendment petitioning activity and is immune from the antitrust laws under the *Noerr-Pennington* doctrine. Stripped of impermissible inferences and conclusory allegations, and viewed in light of the entire citizen petition file, the Complaint fails to allege *any* facts tending to show that the citizen petition was objectively baseless. Accordingly, Rule 12 and the standard set forth in *Prof'l Real Estate Investors* require that this Court dismiss the Complaint in its entirety.

II. LOUISIANA WHOLESALE DOES NOT HAVE STANDING TO ASSERT THE ANTITRUST CLAIMS ALLEGED IN THE COMPLAINT

“Congress did not intend the antitrust laws to provide a remedy in damages for all injuries that might conceivably be traced to an antitrust violation.” *Associated Gen'l Contractors, Inc. v. California State Counsel of Carpenters*, 459 U.S. 519, 534 (1983) (“AGC”). Consequently, an antitrust plaintiff must allege an injury caused by a defendants’ actions *and* demonstrate that it is an appropriate party to vindicate the claim. *Id.* Louisiana Wholesale has failed to do either.

A. Louisiana Wholesale Has Failed to Allege Facts Substantiating Its Claim that Aventis Caused the FDA to Delay the Approval of Generic Leflunomide

Louisiana Wholesale alleges that the citizen petition disguised a scheme to delay FDA approval of generic leflunomide. *See* Compl. ¶ 63 (“As a direct and proximate result of Aventis’ unlawful conduct, [Plaintiffs] were denied the benefits of free and unrestrained competition in the market for leflunomide from March 31, 2005, . . . until September 14, 2005 . . .”). Speculative allegations aside, there is no legal or factual basis for asserting that the citizen petition delayed FDA approval of generic leflunomide.

The Complaint asserts without substantiation that citizen petitions necessarily delay approval of pending ANDAs. *See* Compl. ¶ 42 (alleging that it is “well known” in the industry that FDA withholds approval of ANDAs until after considering and responding to citizen petitions). But the regulations applicable to citizen petitions explicitly prohibit such a delay: the filing of a citizen petition *shall not* “stay or otherwise delay *any* administrative action by the Commissioner,” 21 C.F.R. § 10.35(d) (emphasis added).

Moreover, the letters approving the Generic Manufacturers’ ANDAs (which Louisiana Wholesale must have reviewed in order to ascertain the ANDA approval dates reflected in Paragraph 62 of the Complaint), indicate two important facts: (1) the ANDAs were approved faster than the FDA’s average of twenty months, *see* <http://www.fda.gov/oc/initiatives/generics/whitepaper.html> (last visited on October 15, 2007), and (2) the Generic Manufacturers filed no fewer than *seventeen* amendments to their ANDAs *after* Aventis filed the citizen petition. *See* Exh. 7. At a minimum the amendments suggest either that the citizen petition had merit and the FDA required some action by the Generic Manufacturers, or that the ANDAs were fundamentally deficient and could not be approved without further amendment.

Simply put, any delay in generic competition was a consequence of the statutory and regulatory scheme governing the approval of prescription drugs, and could not have caused the injury about which Louisiana Wholesale complains. *See In re Canadian Imp. Antitrust Litig.*, 470 F.3d 785 (8th Cir. 2006) (affirming dismissal of claim that defendants conspired to prevent the importation of prescription drugs from Canada into the United States, and noting that absence of competition was the result of a federal regulatory scheme, not the consequence of defendants’ actions); *see also RSA Media, Inc. v. AK Media Group, Inc.*, 260 F.3d 10, 15 (1st Cir. 2001) (holding that plaintiff lacked standing because it “was not excluded from the market for outdoor

billboards because of [defendant's] threats,” but “because of the Massachusetts regulatory scheme that prevents new billboards from being built”); *City of Pittsburgh v. West Penn Power Co.*, 147 F.3d 256, 265 (3d Cir. 1998) (determining that plaintiff lacked antitrust standing because “any injury suffered by the City did not flow from the defendants’ conduct, but, rather, from the realities of the regulated environment in which all three were actors”). In short, Louisiana Wholesale has not alleged — and indeed could not allege — any injury fairly traceable to Aventis’ petitioning conduct, and the Complaint should be dismissed for this reason alone.

B. Neither Louisiana Wholesale Nor Any Other Purchaser Plaintiff Would Be an Efficient Enforcer of the Antitrust Laws

Even assuming Louisiana Wholesale had alleged a sufficient nexus between Aventis’ conduct and its alleged injury, the Court must still evaluate whether Louisiana Wholesale is an appropriate and efficient enforcer of the antitrust laws, a question answered by reference to four factors: “(1) the directness or indirectness of the asserted injury; (2) the existence of an identifiable class of persons whose self-interest would normally motivate them to vindicate the public interest in antitrust enforcement; (3) the speculativeness of the alleged injury; and (4) the difficulty of identifying damages and apportioning them among direct and indirect victims so as to avoid duplicative recoveries.” *Volvo N. Am. Corp. v. Men’s Int’l Prof’l Tennis Council*, 857 F.2d 55, 66 (2d Cir. 1988) (quoting *AGC*, 459 U.S. at 540-45) (internal quotation marks omitted). A failure as to any one of these factors may warrant dismissal of a party’s complaint. *Daniel v. Am. Bd. of Emergency Med.*, 428 F.3d 408, 444 (2d Cir. 2005) (affirming dismissal for lack of standing, since more efficient enforcers existed and would be motivated to vindicate the public interest in antitrust enforcement). A failure as to all four requires it. *Paycom Billing Servs., Inc. v. MasterCard Int’l, Inc.*, 467 F.3d 283, 293-94 (2d Cir. 2006) (affirming dismissal where

plaintiffs suffered indirect and speculative injuries, and any remedies would duplicate those available to parties more motivated to vindicate the public's interest in antitrust enforcement).

Louisiana Wholesale cannot satisfy any of these "efficient enforcer" factors. First, any harm it suffered would be wholly derivative of harm suffered by the Generic Manufacturers whose ANDAs were allegedly delayed by Aventis' petitioning conduct. *Cf. Paycom*, 467 F.3d at 293 (noting that Paycom's injuries flowed from the bankcard providers directly harmed by MasterCard's alleged misconduct).

Second, the Generic Manufacturers — not Louisiana Wholesale or any other purchaser plaintiff — would have the greatest interest in vindicating the "public interest in antitrust enforcement" *if* there were a reasoned basis for asserting an antitrust claim on the basis of activity clearly protected by the First Amendment right to petition the government for redress. *Cf. Paycom*, 467 F.3d at 294 (citing *AGC*, 459 U.S. at 542, and observing that the court's refusal to empower Paycom as a "private attorney general" was not likely to "leave a significant antitrust violation undetected or unremedied").

Third, Louisiana Wholesale's claim that the citizen petition delayed the approval and sale of generic leflunomide is entirely speculative and completely self-serving. Even a cursory review of the regulations governing citizen petitions, the complete citizen petition file, and the FDA's letters approving the Generic Manufacturers' ANDAs indicate that any delay in approving generic leflunomide was the result of factors independent of Aventis' petitioning conduct. *Cf. Paycom*, 467 F.3d at 293 (citing *AGC*, 459 U.S. at 542, and rejecting conclusory allegations intending to mask speculative damage claims).

Finally, Louisiana Wholesale fails to satisfy the fourth efficient enforcer factor since it would be difficult to identify any damages and apportion them among Generic Manufacturers

and purchaser plaintiffs who claim that they would have bought generic drugs had they been available sooner. *Cf. Paycom*, 467 F.3d at 293 (observing that apportioning damages “would require wholesale speculation as to the extent and type of all of the various plaintiffs’ injuries,” and the “probability of duplicative recoveries would be very large”); *Laborers Local 17 Health & Benefit Fund v. Philip Morris, Inc.*, 191 F.3d 229, 236 (2d Cir. 1999) (noting that derivative injuries “are generally deemed indirect and as a consequence too remote, as a matter of law, to support recovery”). Having failed all four “efficient enforcer” factors, Louisiana Wholesale lacks antitrust standing to pursue its claims, and its Complaint should be dismissed.

III. LOUISIANA WHOLESALE’S FAILURE TO PLEAD A RELEVANT MARKET REQUIRES DISMISSAL

The Complaint must also be dismissed because Louisiana Wholesale has failed to adequately plead a relevant market. The allegation that a single drug for the treatment of rheumatoid arthritis constitutes the relevant product market fails as a matter of law since the entire citizen petition file (of which the Court may take judicial notice) reveals the existence of multiple substitutable products and because Louisiana Wholesale has alleged *no* facts suggesting that these other drugs are not functionally interchangeable with leflunomide.

To state a claim of monopolization under Section 2 of the Sherman Act, a plaintiff must allege, among other things, that the defendant has monopoly power in a relevant market. *Irvin Indus., Inc. v. Goodyear Aerospace Corp.*, 974 F.2d 241, 244 (2d Cir. 1992). As defining the relevant market is thus a substantive element of a monopolization claim, courts in this Circuit have recognized that a “plaintiff’s failure to define its market by reference to the rule of reasonable interchangeability is, standing alone, valid grounds for dismissal.” *Tower Air, Inc. v. Fed. Express Corp.*, 956 F. Supp. 270, 280 (E.D.N.Y. 1996); *see also Todd v. Exxon Corp.*, 275 F.3d 191, 200 (2d Cir. 2001) (observing that there is “no absolute rule against the dismissal of

antitrust claims for failure to allege a relevant product market.”). And where the plaintiffs’ allegations do not demonstrate an economically coherent market, the claim should be dismissed. *See Apani Sw., Inc. v. Coca-Cola Enters., Inc.*, 300 F.3d 620, 628 (5th Cir. 2002). Thus, for example, where an alleged market is facially too narrow or otherwise improper, courts routinely dismiss antitrust claims. *See, e.g., Queen City Pizza, Inc. v. Domino’s Pizza, Inc.*, 124 F.3d 430, 436 (3d Cir. 1997); *TV Commc’ns. Network, Inc. v. Turner Network Television, Inc.*, 964 F.2d 1022, 1025 (10th Cir. 1992).

It is well settled that the alleged relevant market must be defined in terms of reasonably substitutable products. “If a complaint fails to allege facts regarding substitute products, to distinguish among apparently comparable products, or to allege other pertinent facts relating to cross-elasticity of demand . . . a court may grant a Rule 12(b)(6) motion.” *Re-Alco Indus., Inc. v. Nat’l Ctr. for Health Ed., Inc.*, 812 F. Supp. 387, 391 (S.D.N.Y. 1993); *see also Todd*, 275 F.3d at 200 (“To survive a Rule 12(b)(6) motion to dismiss, an alleged product market must bear a ‘rational relation to the methodology courts prescribe to define a market for antitrust purposes – analysis of the interchangeability of use or the cross-elasticity of demand,’ and it must be ‘plausible.’”) (internal citations omitted). For example, in *Hack v. President & Fellows of Yale College*, the court dismissed a suit alleging that Yale monopolized the market for student housing in New Haven, Connecticut, rejecting plaintiffs’ arguments that the market consisted only of student housing at Yale. 16 F. Supp. 2d 183, 197 (D. Conn. 1998). The court reasoned that students who did not like Yale’s housing policy could choose from hundreds of other “functionally equivalent” universities. *Id.* at 195. The court specifically criticized plaintiffs’ alleged market definition for focusing on the needs of a particular class of plaintiffs, rather than consumers as a whole: “A legally sufficient definition of a relevant market is not defined by

reference to a particular plaintiff, but by reference to services or commodities that are reasonably interchangeable.” *Id.* at 197. The market definition must, in other words, take into account “the commodities or services purchased by general consumers for purposes similar to those of the plaintiff.” *Id.*; *see also Yellow Page Solutions, Inc. v. Bell Atl. Yellow Pages Co.*, No. 00 CIV 5663, 2001 WL 1468168, at *12 (S.D.N.Y. Nov. 19, 2001) (dismissing where plaintiffs alleged a relevant market of Yellow Pages advertising, but failed to allege how Yellow Pages advertising “is in some way unique, that it is a market unto itself” or to show “why other forms of advertising, such as television, radio, or other print media, are not reasonably interchangeable with Yellow Pages advertising”).⁸

Courts analyzing allegations about prescription drug markets have routinely applied these standards and dismissed deficient complaints. The relevant market may consist of a single drug, a class of drugs or an entire range of treatments for a particular condition. *See, e.g., United States v. Ciba Geigy Corp.*, 508 F. Supp. 1118, 1155 (D.N.J. 1976) (defining the relevant market as all hypertension drugs because they were medically interchangeable); *SmithKline Corp. v. Eli Lilly & Co.*, 427 F. Supp. 1089, 1098 (E.D. Pa. 1976) (limiting relevant market to class of antibiotics, rather than all antibiotics, due to “divergent therapeutic indications” and lack of cross elasticity of demand). But the fact that a drug is a unique chemical compound is not enough to limit the relevant market to that drug; rather, there must be evidence of distinctive uses and lack of substitutes in order to so narrowly define the relevant market. *See, e.g., SmithKline*, 427 F.

⁸ *See also, e.g., Commercial Data Servers, Inc. v. Int’l Bus. Machs. Corp.*, 166 F. Supp. 2d 891, 896 (S.D.N.Y. 2001) (dismissing complaint that “does not explain why these other [products] would not be functionally interchangeable with, and/or exhibit cross-elasticity of demand for” the alleged relevant product); *E. & G. Gabriel v. Gabriel Bros., Inc.*, No. 93 CIV 0894, 1994 WL 369147, at *4 (S.D.N.Y. 1994) (“Plaintiff’s failure to allege a plausible product market is fatal to its claim.”); *see also Queen City Pizza, Inc. v. Domino’s Pizza, Inc.*, 124 F.3d 430, 436 (3d Cir. 1997) (“Where the plaintiff fails to define its proposed relevant market with reference to the rule of reasonable interchangeability and cross-elasticity of demand, or alleges a proposed relevant market that clearly does not encompass all interchangeable substitute products . . . a motion to dismiss may be granted.”).

Supp. at 1098 (holding class of antibiotics had “sufficient peculiar characteristics and uses to make them a distinguishable product market”).

Given these standards, Louisiana Wholesale’s attempt to plead a relevant product market falls short of the required mark. The allegation that the relevant market is limited to a *single* drug for the treatment of rheumatoid arthritis, is belied by the citizen petition itself (*see* Exhibit 1 at nn. 15 and 16) and the entire citizen petition file, which clearly demonstrate the availability of numerous other drugs. *See, e.g.*, Scottish Intercollegiate Guidelines Network, *Management of Early Rheumatoid Arthritis*, 7-17 (Dec. 2000) (the “Guidelines”) (attached hereto as Exh. 1, Tab 6). According to the Guidelines, leflunomide is just one of several drugs within the class of “Disease Modifying Anti-Rheumatic Drugs,” including hydroxychloroquine, sulphasalazine, methotrexate, IM gold, penicillamine, auranofin, azathioprine, leflunomide, and cyclosporine. *Id.* at 12. Moreover, the Guidelines conclude that leflunomide has “comparable efficacy” with methotrexate and sulphasalazine. *Id.* at 11, 12.

In short, the Complaint utterly fails to address the fact that there are numerous other disease-modifying drugs available to treat rheumatoid arthritis or to explain why these drugs should be excluded from a self-serving definition of the relevant market. To the contrary, Louisiana Wholesale has alleged only that there are “no reasonably interchangeable drug products available to prescribing physicians for the indications for which leflunomide is prescribed.” Compl. ¶ 74. This conclusory allegation is at odds with the facts reflected in the documents upon which the Complaint relies and wholly insufficient as a matter of law.

CONCLUSION

For the foregoing reasons, Aventis respectfully requests that the Court dismiss the Complaint under Federal Rule of Civil Procedure 12(b)(6).

Dated: October 15, 2007

Respectfully submitted,

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CERTIFICATE OF SERVICE

I, Christopher R. Farrell, certify that the foregoing Memorandum of Points and Authorities was served on October 15, 2007, on the counsel listed below in the manner(s) indicated below:

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